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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,091	08/15/2005	George B. Stefano	R1381-200US	6473

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HOFFMAN WARNICK LLC
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EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1655

NOTIFICATION DATE	DELIVERY MODE
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09/16/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOCommunications@hoffmanwarnick.com

Office Action Summary	Application No. 10/526,091	Applicant(s) STEFANO ET AL.	
	Examiner Randall Winston	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 19-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of receipt and entry of the amendment filed on 06/16/2010.

The rejection made under 35 USC 112, second paragraph, set forth in the previous office action has been overcome.

Claims 1-7 and 19-31 have been examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is rendered vague and indefinite because of the phrase "effective amount of extract of *Salix alba* extract is." Examiner suggests inserting the phrase "wherein the *Salix alba* extract is" after the phrase "an effective amount of extract of *Salix alba*" for consistency and clarity.

Claim 19(e) is rendered vague and indefinite because of the phrase "extracting the effective amount of extract by." Examiner suggests deleting the phrase "extracting the effective amount of extract by" and also inserting after the term "chromatography" the phrase "to obtain said extract." for consistency and clarity.

Claim 20 is rendered vague and indefinite because of the phrase "effective amount of." Examiner suggests deleting the phrase "effective amount of" for consistency and clarity.

Claim 22 is rendered vague and indefinite because of the phrase "effective amount of." Examiner suggests deleting the phrase "effective amount of" for consistency and clarity.

Claim 22 is rendered vague and indefinite because the claim does not have a period after the term "Daltons." Examiner suggests placing a period after the term "Dalton" for consistency and clarity.

Claim 24 is rendered vague and indefinite because of the phrase "further comprising." Examiner suggests deleting the phrase "furthering comprising" and replacing the phrase with "wherein the composition has" for consistency and clarity.

Claim 25 is rendered vague and indefinite because of the phrase "further comprising." Examiner suggests deleting the phrase "furthering comprising" and replacing the phrase with "wherein the composition has" for consistency and clarity.

Claim 26 is rendered vague and indefinite because of the phrase "further comprising." Examiner suggests deleting the phrase "furthering comprising" and replacing the phrase with "wherein said extract displays" for consistency and clarity.

Claim 27 is rendered vague and indefinite because of the phrase "A method comprising." Examiner suggests deleting the phrase "A method comprising" and replacing the phrase with "A method of preparing a *Salix alba* extract" for consistency and clarity.

Claim 27 is rendered vague and indefinite because of the phrase “extracting the effective amount of extract by.” Examiner suggests deleting the phrase “extracting the effective amount of extract by” and also inserting after the term “chromatography” the phrase “to obtain said extract.” for consistency and clarity.

Claim 28 is rendered vague and indefinite because of the phrase “effective amount of.” Examiner suggests deleting the phrase “effective amount of” for consistency and clarity.

Claim 29 is rendered vague and indefinite because of the phrase “effective amount of.” Examiner suggests deleting the phrase “effective amount of” for consistency and clarity.

Claim 30 is rendered vague and indefinite because of the phrase “effective amount of.” Examiner suggests deleting the phrase “effective amount of” for consistency and clarity.

Claim 30 is rendered vague and indefinite because the claim does not have a period after the term “Daltons.” Examiner suggests placing a period after the term “Dalton” for consistency and clarity.

Claim 31 is rendered vague and indefinite because of the phrase “effective amount of.” Examiner suggests deleting the phrase “effective amount of” for consistency and clarity.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 stand rejected under 35 U.S.C. 102(e) as being anticipated by or in the alternative, under 35 U.S.C. 103(a) as being obvious over (PDR for Herbal Medicines, First Edition, *Salix Species*, pages 1111-1112, copyrighted 1998) or (The Healing Herbs, The Ultimate Guide to the Curative Power of nature's Medicines, *White Willow*, pages 369-371, copyrighted 1991) for the same reasons set forth in the previous OFFICE ACTION which are restated below.

Applicant claims a pharmaceutical composition comprising a water extract of *Salix alba* (i.e. the bark and/or leave and/or flower) whereas the water soluble extract

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contains water soluble components and/or compounds having a claimed molecular weight therein.

PDR for Herbal Medicine reference as well as The Healing Herb reference each teach a pharmaceutical composition which appears to be the same as that instantly claimed since both the claimed invention and each of the reference compositions comprise a water extract of the bark (i.e. the bark is in powdered form) of the same *Salix alba* species. Therefore, when The PDR for Herbal Medicine reference or The Healing Herb's reference performs the same extraction process of extracting the bark of the same *Salix alba* species with the same solvent such as water as the claimed invention's extraction process, both extraction processes of the cited references and the claimed invention would both inherently contain water soluble components and/or compounds having the claimed molecular weight therein (see, e.g. PDR for Herbal Medicine entire abstract including pages 1111-1112, especially under preparation or The Healing Herb entire abstract including pages 369-371 especially page 371 under RX for White Willow). Therefore, reference is deemed to anticipate the claimed invention.

In the alternative, even if the claimed composition is not identical to the referenced composition in regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to inherently possess the same characteristics which they have been shown. Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please note, the intended use of the above claimed composition (i.e. the functional effects and/or properties instantly claimed would be inherent to the prior art reference) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Applicant's argument has been carefully considered but it is not deemed persuasive. Applicant argues that Applicant continues to assert the arguments presented in concerning the rejection of claims 1-7 in the Amendment filed on April 15, 2009. However, Examiner maintains that for the reasons fully set forth above under

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USC 102/103 rejection, the above cited reference of PDR for Herbal Medicines anticipates by or in the alternative, under 35 U.S.C. 103(a) as being obvious over the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655